

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

#### Protocol summary

##### Study aim

Determining the impact of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

##### Design

After selecting the samples, they will be divided into two groups using a random block of 6 and with an allocation ratio of 1.1. Each of the blocks will have 3 people from the control group and 3 people from the intervention group. It is random.

##### Settings and conduct

Samples are collected in 17 Shahrivar and Abu Dhar centers. The samples will be selected from among the mothers who are eligible and who meet the entry criteria and do not have the exit criteria. To hide the random allocation, the type of intervention will be written on paper and placed inside the opaque envelopes numbered consecutively. In this way, the researcher and the participant will not know the type of intervention until the start of the intervention. Due to the nature of this study, blinding will not be possible.

##### Participants/Inclusion and exclusion criteria

Entry conditions: primiparous mothers 6 months after giving birth - mothers with poor sleep - absence of any mental and physical illness - natural and uncomplicated birth - birth of a healthy and mature baby - singleton - exclusive breastfeeding - at least the end of primary school education - Age range - 1 to 40 years - proficient in Persian language Conditions of non-entry: postpartum depression - hospitalization of the baby for any reason - suffering from an acute febrile illness during research - suffering from chronic diseases such as diabetes

##### Intervention groups

This research is a type of clinical trial intervention that investigates the effect of cognitive-behavioral counseling based on mindfulness on the quality of sleep of mothers with first-born children in the postpartum period.

#### Main outcome variables

Sleep quality in the Pittsburgh Questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230718058833N1**

Registration date: **2023-08-29, 1402/06/07**

Registration timing: **prospective**

Last update: **2023-08-29, 1402/06/07**

Update count: **0**

##### Registration date

2023-08-29, 1402/06/07

##### Registrant information

##### Name

Simin Khezri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3353 5404

##### Email address

khezri.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-03, 1402/06/12

##### Expected recruitment end date

2024-01-02, 1402/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

**Public title**  
Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of mothers

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Primiparous mothers six months after delivery  
Absence of any mental or physical illness  
Natural birth without complications  
The birth of a healthy and mature baby  
monogamy  
Exclusive breastfeeding  
Minimum education at the end of elementary school  
Age range from 18 to 40 years  
Proficient in Persian language

**Exclusion criteria:**

Postpartum depression (getting a score above 5.12 from the Edinburgh Depression Questionnaire)  
Hospitalization of the baby for any reason  
Getting an acute febrile illness during research  
Having chronic diseases such as diabetes

**Age**  
From **18 years** old to **40 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **98**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After the initial selection of the samples, they will be divided into two groups using a random block of 6 and with an allocation ratio of 1.1. In each of the blocks, 3 people will be in the control group and 3 people will be in the intervention group. He is a random person.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**

Not used

**Assignment**  
Other

**Other design features**  
In order to hide the random allocation, the type of intervention will be written on paper and placed inside opaque envelopes numbered consecutively, in this way, the researcher and the participant will not know the type of intervention until the intervention begins. This study will not be able to blind the researcher and the participant.

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Ahvaz University of Medical Sciences

**Street address**

Golestan St., Jundishapur University of Medical Sciences, Ahvaz, Nursing and Midwifery College

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715749

**Approval date**

2023-08-15, 1402/05/24

**Ethics committee reference number**

IR.AJUMS.REC.1402.289

**Health conditions studied**

1

**Description of health condition studied**

Sleep quality

**ICD-10 code**

G47

**ICD-10 code description**

Sleep disorders

**Primary outcomes**

1

**Description**

Sleep quality in the Pittsburgh Questionnaire<sup>۱</sup>

**Timepoint**

At the beginning of the study, week 8 (immediately after the intervention), week 12 after the intervention (one month after the intervention)<sup>۲</sup>

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire-Edinburgh Depression Scale

**Secondary outcomes**

1

**Description**

Sleep quality score

**Timepoint**

8 weeks (immediately after the intervention) and 12 weeks after the intervention

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire-Edinburgh

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will be divided into 4 groups, then the intervention will be carried out in the form of a pre-test, post-test and follow-up stage, so that all the mothers of the intervention and control groups at the beginning of the study, week 8 and week 12 after the intervention of the sleep quality questionnaire will be completed by self-reporting. The purpose of this study is to determine the effectiveness of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period. and if they have entry criteria and no exit criteria, the samples will be selected, at first, each eligible person will be given the same explanation about the objectives of the research and how to intervene. Completing the demographic questionnaire, the Edinburgh Depression Scale and the sleep quality questionnaire by Samples that meet the conditions for entering the study will be conducted. Counseling will be conducted by a trained researcher under the supervision of a consultant professor at the center. The women of the intervention group will undergo 8 group counseling sessions (1 session per week) with a cognitive therapy approach based on Mindfulness will be aimed at improving the quality of sleep. Sessions will be held in groups, one 45-minute session per week for 2 months according to the plan between the consultant and the clients.

#### Category

Behavior

### 2

#### Description

Control group: Control group: This group consists of 49 people. In each of the blocks, 3 people will belong to the control group and 3 people will belong to the intervention group, and the order of placement of each person is random. Low sleepers will not receive any intervention, in order to comply with ethical standards, they will be given a training booklet and a summary of the contents of the sessions.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Seventeen Shahrivar Health Center

##### Full name of responsible person

Dr. Naheed Javadi Far

##### Street address

Thirty meters, Rostagari Street, Gandami Street

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8331

#### Email

nahidjavadifar\_341@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Abu Dhar Health Center

##### Full name of responsible person

Dr. Naheed Javadi Far

##### Street address

Ahvaz

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#### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mehrnoosh Zaker Kish

##### Street address

Ahvaz Academic City - Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences, Ahvaz - ground floor

#### City

Ahvaz

#### Province

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6135715749

#### Phone

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#### Email

zakerkish-m@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ahvaz University of Medical Sciences

#### Proportion provided by this source

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Naheed Javadi Far

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Khuzestan, Ahvaz, Golestan St., Jundishapur  
University of Medical Sciences, Ahvaz Faculty of  
Nursing and Midwifery

**City**

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Khuzestan

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**Phone**

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Naheed Javadi Far

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

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Sciences, Ahvaz Faculty of Nursing and Midwifery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Simin Khezri

**Position**

Master's student in counseling in midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Behesht Sadegh Square, Shahid Korehbandi Street,  
Plate 12

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7514873456

**Phone**

+98 77 3353 5404

**Email**

khezri.s@ajums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only part of the demographic information of the patients  
and the main outcome can be shared.

**When the data will become available and for how long**

6 months after the results are published

**To whom data/document is available**

The data will be available only to researchers working in  
academic and scientific institutions.

**Under which criteria data/document could be used**

Mentioning the name of the study and mentioning the  
name of the researchers

**From where data/document is obtainable**

Simin Khezri, Faculty of Nursing and Midwifery,  
Jundishapur University of Medical Sciences, Ahvaz  
**What processes are involved for a request to access**

**data/document**

A maximum of one month after the request

**Comments**